



PATENT
Customer No. 22,852
Attorney Docket No. 03715.0110

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Jean-Pierre BENOIT et al.)	Group Art Unit: 1711
)	
Application No.: 10/069,405)	Examiner: Tran, Thao T.
)	
Filed: May 29, 2002)	Confirmation No.: 3630
)	
For: METHOD FOR ENCAPSULATING ACTIVE)	
SUBSTANCES BY COACERVATION OF)	
POLYMERS IN NON-CHLORINATED)	
ORGANIC SOLVENT)	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In accordance with the provisions in the Patent and Trademark Office Official Gazette Notice entitled "New Pre-Appeal Brief Conference Pilot Program" of July 12, 2005, Applicants respectfully request a pre-appeal brief review of the rejections in the Final Office Action dated July 28, 2006 (Office Action). This Request is being filed concurrently with a Notice of Appeal, before the filing of an Appeal Brief, and complies with the requirements set forth in the aforementioned Official Gazette Notice. A Petition for a One-month Extension of Time and the requisite fee are also being filed concurrently with this Request.



REMARKS

I. Status of the claims

Claims 1, 3-21, and 25-41 have been at least twice rejected and are the only pending claims in this application. No claim is being amended in this Request.

II. Claim rejections under 35 U.S.C. § 102

The Office rejected claims 1, 3-21, 25-31, and 33-41 under 35 U.S.C. § 102 as allegedly being anticipated by WO 95/13799. Applicants traverse this rejection.

WO 95/13799 fails to meet all of the limitations of the claims

The Office argues that WO 95/13799 discloses as a non-solvent "a solvent blend including at least two of the following: an ester, an alcohol, and a ketone" citing WO 95/13799 at p. 15, ¶ 3. Office Action at p. 5. The Office further argues that WO 95/13799 "uses water and/or an aqueous solution in the second phase and as a quenching liquid." *Id.* The Office concludes that the "use of an alcohol . . . and water in the second phase would meet [respectively] the requirement[s] of the non-solvent and curing agent in the instantly claimed invention." *Id.* Under these circumstances, however, the Office has not explained which element from WO 95/13799 would correspond to the "organic solvent" in step (a) of instant claim 1. In order to anticipate a claim, the Office must show that a single reference contains all of the elements of the claim. M.P.E.P. § 2131. The Office has not met this burden.

In the absence of an explicit statement, and under the best possible interpretation of the Office's arguments, Applicants understand that the Office believes the same solvent blend, capable of comprising ethyl acetate and an alcohol, meets the requirements of both the "organic solvent" and the "non-solvent" of the instant invention.

Such position is clearly incorrect because coacervation requires that: 1) the organic solvent dissolve the polymer in an initial step, and 2) the non-solvent lower the solubility of the polymer so that the polymer is deposited on the active principle, encapsulating it. Specification

at p. 5, lines 1-11. Therefore, the same solvent (or solvent blend) cannot perform the functions of the "organic solvent" and the "non-solvent" at the same time.

Applicants note that there is no single embodiment in WO 95/13799 (described either broadly or particularly) that would meet the limitations of the "organic solvent" and the "non-solvent" recited in the instant claims. For at least this reason, Applicants respectfully request that this rejection be withdrawn.

The Office has not used the proper standard for anticipation

Moreover, the Office has failed to show that WO 95/13799 discloses all of the *method steps* instantly claimed. Throughout prosecution the Office seemed more concerned with finding equivalents in WO 95/13799 for Applicants' solvents, non-solvents, and curing agents, than with explaining how WO 95/13799 met the claimed method steps.

The Office cites to Figures 1-3; p. 9, ¶ 3; and p. 15, ¶¶ 2-3 of WO 95/13799 as allegedly disclosing the claimed invention. Office Action at p. 2. The figures and the passages show a method comprising:

- 1) preparing a first phase comprising a polymer and an active ingredient dissolved or dispersed in a solvent blend (mutually miscible solvents; *i.e.* a single phase) (p. 9; *see also* bottom of p. 13). The solvent blend may comprise "at least two of the following: an ester, an alcohol, and a ketone" (p.15);
- 2) preparing a second phase comprising an aqueous solution, which is immiscible with the first phase (p. 9; *see also* the "Summary of Invention" at p. 8, lines 10-11);
- 3) combining the first and second phases (p. 9); and
- 4) isolating the microparticles formed in step (c) (p. 9).

As mentioned previously, in order to anticipate a claim, a single reference must contain all of the elements of the claim. M.P.E.P. § 2131. Additionally, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim" and "[t]he elements must be arranged as required by the claim." *Id.* (emphasis added, internal citations omitted).

The method cited by the Office clearly fails to show the step of "adding a non-solvent to the solution of polymer, which allows deposition of the polymer at the surface of the active

principle” as instantly claimed. Even if the Office believes that the solvent blend used in step (1) above can be used as a non-solvent, there is no polymer deposition in step (1) of the method disclosed in WO 95/13799.

If, on the other hand, the Office argues that the second phase in WO 95/13799 corresponds to Applicants non-solvent, then such second phase fails to meet the instant limitation wherein the non-solvent “is miscible with said organic solvent.”

The foregoing remarks make it abundantly evident that the cited method in WO 95/13799 does not anticipate the claimed invention.

No disclosure in WO 95/13799 anticipates the instant invention

The passages from WO 95/13799 cited by the Office and discussed above relate to a technique commonly known in the art as “solvent extraction.” See, e.g., WO 95/13799 at p. 8, lines 14-16; p. 29, lines 4-9. As mentioned above, this technique fails to anticipate the claimed invention.

WO 95/13799 also discloses a coacervation technique in which a non-solvent is used. See, e.g., p. 5, line 9 to p. 6, line 2; p. 29, lines 4-17; and Examples 11-14. This technique is similar to the prior art coacervation techniques disclosed in the instant specification (p. 7, lines 22-25). The coacervation method of WO 95/13799 also fails to anticipate the claimed invention because it uses silicon oil as the non-solvent (*i.e.*, not the claimed alcohol or ketone) and heptane as the curing agent (*i.e.*, not the claimed water, alcohols, or mixtures thereof).

III. Claim rejections under 35 U.S.C. § 103

The Office rejected claim 32 under 35 U.S.C. § 103 as allegedly being unpatentable over WO 95/13799. Applicants traverse this rejection. The Office relied on the arguments discussed above to meet all of the limitations of claim 32, except the limitation regarding the coacervation temperature being equal to -4° C. The Office argued that it would have been obvious to adjust the coacervation temperature “in order to bring forth maximal benefits.” As mentioned before, WO 95/13799 fails to meet the limitations of the claimed invention and the Office’s arguments

regarding adjustment of the temperature fail to cure the deficiencies cited above. For at least this reason, Applicants respectfully request that this rejection be withdrawn.

IV. Conclusions

In view of the foregoing remarks, Applicants respectfully request reconsideration of the rejections in the Final Office Action and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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